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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,093	05/02/2006	Paula Fernstrom	1103326-0740	4676

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PATENT DEPARTMENT
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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,093	FERNSTROM ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-37* is/are pending in the application.

4a) Of the above claim(s) *24-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/2/2006; 5/1/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

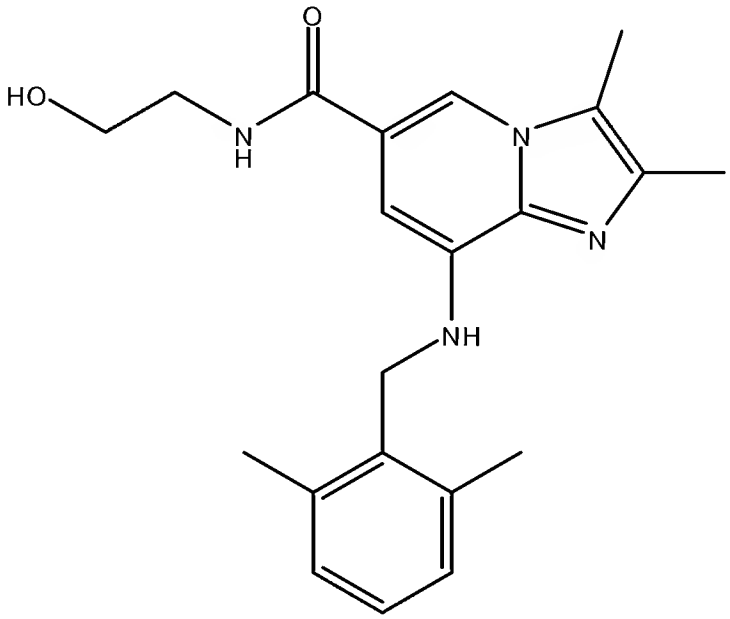
DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 10/20/2008 is acknowledged (it is noted that the traverse only applies to Groups I & II, but not to Groups III-VIII, which applicant acknowledged are withdrawn). The traversal, only with regard to Groups I & II, is on the ground(s) that Groups I & II are directed to a new use of a potassium-competitive acid blocker (P-CAB), i.e., the treatment of sleep disturbance due to silent gastroesophageal reflux ("GERD"), which involves a different patient population than symptomatic GERD, in which the patient has heartburn or other typical reflux symptoms; that although the prior art cited (Amin et al.; WO 99/55706) teaches P-CAB compounds which may be used for the prevention and treatment of gastrointestinal inflammatory diseases and gastric acid related diseases, the target population of the claimed method does not experience typical reflux symptoms. As such, the special technical feature of Groups I & II, i.e., the administration of a P-CAB for the treatment of silent GERD, defines a contribution over the art. This is not found persuasive because 1) While the compounds of the two Groups do not share a common structural feature, it is noted that they share a common activity (P-CAB). Applicant's argument with respect to the limited patient population of Groups I & II is noted: the technical feature linking Groups I & II (and also the compound species within these two groups, species (i) in the 10/7/2008 Restriction Requirement, when limited to Groups I & II) is the administration of a P-CAB for the treatment of the condition of sleep disturbance due to silent GERD.

However the argument that Groups I & II are linked by a "special" technical feature is not found persuasive for the following reason: in addition to the previous rationale used to demonstrate lack of unity between Groups I (or II) and all other groups, the following additional rationale demonstrates unity is also lacking between Groups I & II, taking note of applicant's argument that the technical feature between Groups I & II (as well as the species within these groups) would be the administration of a P-CAB for the treatment of sleep disturbances associated with silent GERD. This technical feature is not a "special" technical feature, as it does not define a contribution over the prior art; the technical feature linking the Groups (and species) lacks inventive step with respect to this feature, for the same reasons that are given below in the rejection under 35 USC 103, based on the references Amin et al. (WO 99/55706; 1999; IDS 5/2/2006 reference) and either of the following: Harding ("Nocturnal asthma: role of nocturnal gastroesophageal reflux"; 1999; Chronobiology International; 16(5): 641-62; abstract; PMID: 10513887) or Carr et al. ("Case Report: Severe non-obstructive sleep disturbance as an initial presentation of gastroesophageal reflux disease"; 1999: International Journal of Pediatric Otorhinolaryngology' 51: 115-120; IDS 5/1/2007reference, Cite No. C), which is outlined below. Since the technical feature is lacks inventive step, based on the combined references, the technical feature does not constitute a special technical feature as it does not define a contribution over the prior art. Accordingly, the inventions (and species) are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept, unity is lacking, and the restriction and specie election requirements are maintained.

2. Applicant's election with traverse of 2,3-dimethyl-8-(2,6-dimethylbenzylamino)-N-hydroxyethyl-imidazo[1,2-a]pyridlne-6-carboxamide, given by the formula:



with the identification that claims 20-23 of Group I read on the elected specie in the reply filed on 10/20/2008 is acknowledged. The traversal is on the ground(s) that for the reasons discussed above. This is not found persuasive because for the same reasons outlined above.

3. Claims 25-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/20/2008.

4. Claim 24 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/20/2008.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amin et al. (WO 99/55706; 1999; IDS 5/2/2006 reference) and either of the following: Harding ("Nocturnal asthma: role of nocturnal gastroesophageal reflux"; 1999;

Chronobiology International; 16(5): 641-62) or Carr et al. ("Case Report: Severe non-obstructive sleep disturbance as an initial presentation of gastroesophageal reflux disease"; 1999: International Journal of Pediatric Otorhinolaryngology' 51: 115-120; IDS 5/1/2007reference, Cite No. C).

Amin teaches imidazo pyridine compounds of the same formula as instant formula I, which inhibit exogenously or endogenously stimulated gastric acid secretion and thus can be used in the prevention and treatment of gastrointestinal inflammatory diseases (abstract); the compounds taught include the elected compound (p. 5, lines 5-6; p. 23, Example 1.3; claim 4, 2nd compound); the compounds are effective as inhibitors of the gastrointestinal H^+, K^+-ATPase and thereby as inhibitors of gastric acid secretion (p. 1, line 29 – p. 2, line 2); the compounds may be used for treatment of gastric acid-related diseases in mammals including man, such as reflux esophagitis, and other gastrointestinal disorders where gastric antisecretory effect is desirable, in patients with conditions, that include preventing acid aspiration (p. 15, lines 15-22); administration of a typical daily dose (i.e., an effective amount) to a patient (p. 15, lines 25-27). Amin does not teach application of the method to the specific population group of patients with silent GERD that have sleep disturbance.

Harding teaches 24% of those with asthma that is difficult to control have "clinically silent" Gastroesophageal reflux (GER) (abstract); most asthmatics with GER also have abnormal esophageal acid contact times while in the supine position, reflecting sleep time (abstract); esophageal acid infusions caused more airway responses at 04:00 than 24:00; a positive correlation between reflux score and

nighttime-associated wheezing (abstract). The nighttime-associated wheezing (correlated to reflux score) would be a sleep disturbance due to silent GERD.

Carr teaches severe non-obstructive sleep disturbance was an initial presentation of a child with gastroesophageal reflux disease (title); the child treated had atypical symptoms of GERD (silent GERD; abstract); the sleep disturbance resolved quickly after treatment of GERD (abstract); treatment of GERD includes proton pump inhibitors (p. 119, 2nd paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the generic method of treating gastric acid related diseases, taught by Amin, to the specific condition within this genus of sleep disturbance associated with silent GERD, recognized as a problem by both Harding and Carr with different sleep-related symptoms recognized, giving the elected method of the instant claims. The motivation to administer the elected compound would have been the art-recognized expectation of reduction of esophagus acid levels during the night. Absent evidence to the contrary, there would have been a reasonable expectation of success, based on the expectation of reducing gastric acid levels in the patient during the night, thereby reducing the disturbances to sleep caused by reflux episodes.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 20-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-6 of copending Application No. 11/912954 in view of Amin et al. (WO 99/55706; 1999; IDS 5/2/2006 reference) and Carr et al. ("Case Report: Severe non-obstructive sleep disturbance as an initial presentation of gastroesophageal reflux disease"; 1999: International Journal of Pediatric Otorhinolaryngology' 51: 115-120; IDS 5/1/2007reference, Cite No. C).

The copending claims and the instant claims are both directed to a method for the treatment of sleep disturbance due to silent gastro-esophageal reflux, comprising administering an effective amount of a compound to a patient in need thereof. The claims differ in that the instant claims involve administration of a P-CAB compound, whereas the copending claims involve a proton pump inhibitor (PPI). Amin teaches imidazo pyridine compounds of the same formula as instant formula I, which inhibit exogenously or endogenously stimulated gastric acid secretion and thus can be used in the prevention and treatment of gastrointestinal inflammatory diseases (abstract); the compounds taught include the elected compound (p. 5, lines 5-6; p. 23, Example 1.3;

claim 4, 2nd compound); the compounds are effective as inhibitors of the gastrointestinal H^+, K^+-ATPase and thereby as inhibitors of gastric acid secretion (p. 1, line 29 – p. 2, line 2). Carr teaches severe non-obstructive sleep disturbance was an initial presentation of a child with gastroesophageal reflux disease (title); the child treated had atypical symptoms of GERD (silent GERD; abstract); the sleep disturbance resolved quickly after treatment of GERD (abstract); treatment of GERD includes proton pump inhibitors (p. 119, 2nd paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the elected compound for the copending compounds, giving the instant claimed method. The motivation would have been the art recognized activity of both compounds in inhibiting gastric acid secretion and treating gastroesophageal reflux, both of which would be expected to also be effective in treating the more specific condition of sleep disturbance due to silent gastro-esophageal reflux.

This is a provisional obviousness-type double patenting rejection.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614